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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,624	02/20/2004	Ricardo E. Paxson	MWS-110RCE2	7212

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EXAMINER	
SIMS, JASON M	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,624	PAXSON ET AL.	
	Examiner	Art Unit	
	JASON M. SIMS	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 45-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 45-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/8/2009 has been entered.

Applicant's arguments, filed 6/8/2009, have been fully considered. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 6/8/2009, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 1-22 and 45-48 are the current claims hereby under examination.

The following rejection is being maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-22 and 45-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Sauro et al. (2003).

The claims are directed to a system for improved simulation of a biological system comprising a plurality of chemical reactions, they system comprising:

a storage device; and

a processor configured to:

construct a composite graphical model of a biological system including a first chemical reaction and a second chemical reaction, the composite graphical model having components described by at least two different types of mathematical models and including a specified constraint provided in addition to the first and second chemical reactions that constrains dynamic behavior of the biological system,

accept as input the constructed composite graphical model of the biological system,

execute the composite graphical model to generate as output dynamic behavior of the biological system using a first type of computational model for the first chemical reaction, and a second type of computational model for the second chemical reaction, and the specified constraint, the executing involving evaluating the at least two different types of mathematical models, and

store the dynamic behavior of the biological system in the storage.

Sauro et al. show a system, computer-implemented method, and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling

component with a graphical user interface (GUI) to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biological system; and an analysis environment to display the dynamic behavior (figure 11). In figure 11 and figure 12 of Sauro et al, the elements of modeling component having a GUI providing means for accepting user input via a tool palette to generate a block diagram of a plurality of related chemical reactions that make a biological system. The figure also depicts an analysis environment displaying the dynamic behavior of the biological system, and a simulation engine. Sauro et al describe that the goal of the BioSPICE is to create an open source framework and toolset for modeling dynamic cellular network functions (page 355, first paragraph). Furthermore, Sauro et al. at page 364 describe how the System Biology Workbench (SBW) interfaces with Jarnac, wherein the Jarnac model instances can be created and destroyed through the modelServices in the SBW interface. Examples of Jarnac models are ones that simulate continuous (ODE based) or probabilistic (based on the Gillespie methods). Applicant defines at paragraph [0095] of the published application that a composite system has components that fall into the four types of models discussed in previous paragraphs, such as paragraph [0093], wherein the modeling implements difference equations, such as ODEs. Thus, it is being interpreted that a composite graphical model is one which implements difference equations such as ODEs for simulating dynamic behaviors. Therefore, the SBW interface, which interacts with Jarnac and runs and executes simulation models

that implement ODEs and probabilistic models reads on a processor configured to construct and execute composite graphical models.

In addition, Sauro et al. discloses the capabilities of simulating the dynamic behavior along with the ease of annotating and editing within the JDesigner environment. Moreover, Sauro teaches at page 364 that Jarnac enables modifying, through the SBW interface, the parameters and initial conditions, i.e. annotating the graphical model in response to a user requesting to add annotations to the model that are provided by the user. In addition, Sauro teaches that JDesigner also has annotating capabilities to support layout information upon request by a user. Furthermore, the JDesigner environment works well with the Jarnac environment to build an easy to use systems biology development environment. With regards to applicant's newly added means plus functional language in claim 45, Suaro teaches at page 365, first two lines, that the Jarnac application has the means for generating dynamic behavior of the modeled biological system, which actually carries out the simulation and is executed through the SBW interface.

Response to Arguments

Applicant's arguments filed 6/8/2009 have been fully considered but they are not persuasive.

Applicant argues that Sauro fails to disclose or suggest at least the following feature of claim 1: executing the composite graphical model to generate as output dynamic behavior of the biological system using a first type of

computational model for the first reaction, and a second type of computational model for the second chemical reaction, and the specified constraints, the executing involving the at least two different types of mathematical models.

Applicant's arguments are not found persuasive as Sauro et al. at page 355, first paragraph states that "Like SBW, the goal of the BioSPICE project (BioSPICE 2001) is to create an open source framework and toolset for modeling dynamic cellular network functions. Furthermore, applicant defines at paragraph [0095] of the published application that a composite system has components that fall into the four types of models discussed in previous paragraphs, such as paragraph [0093], wherein the modeling implements difference equations, such as ODEs. Thus, it is being interpreted that a composite graphical model is one which implements difference equations such as ODEs for simulating dynamic behaviors. Sauro et al. at page 364 describe how the System Biology Workbench (SBW) interfaces with Jarnac, wherein the Jarnac model instances can be created and destroyed through the modelServices in the SBW interface. Examples of Jarnac models are ones that simulate continuous (ODE based) or probabilistic (based on the Gillespie methods). Thus the modeling capabilities of Jarnac read on a composite graphical model of a biological system. In addition Sauro et al. at page 356, in the section about Architecture, describe how the modules in the SBW framework are executed through user requests and program commands.

Applicant argues that none of the cited passages address executing a composite graphical model of a biological system.

Applicant's arguments are not found persuasive because Sauro et al. at page 364 describes how the SBW interfaces with the Jarnac environment, which executes the models either via a user or program control wherein several models can be run simulataneously. Thus, the SBW interface enables the execution of the Jarnac composite graphical models and reads on the claim limitation.

Applicant argues that SBW does not create models or execute models at all.

Applicant's arguments are not found persuasive as Sauro et al. at page 364 describes the SBW interface which interfaces with Jarnac to create and run models.

Applicant further argues that Sauro et al. only describe examples of non-composite models.

Applicant's arguments are not found persuasive as Sauro et al. at page 364 describe how modules can have a number of reactions, which are describe by model equations, such as "differential equations, the rate law expressions, and the list of any conservation laws in the model." Applicant defines at paragraph [0095] of the published application that a composite system has components that fall into the four types of models discussed in previous paragraphs, such as paragraph [0093], wherein the modeling implements difference equations, such as ODEs. Thus, it is being interpreted that a composite graphical model is one which implements difference equations such as ODEs for simulating dynamic behaviors, such as taught by Sauro et al.

Maintained:

Claims 1-5, 8-11, 14-17, 20-22, 45, 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Hucka et al. (Pacific Symposium on Biocomputing Vol. 7, p.450-461, 2002).

Hucka et al. show a system, computer-implemented method, and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component with a graphical user interface to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to display the dynamic behavior (figures 1 and 2). Hucka et al. describe Jdesigner, a software providing a GUI to accept user commands and data (sect. 5.2). Jdesigner provides a tool palette aiding in the construction of the of a block diagram model, as is seen in figure 1 (figure 1 and p. 452). As shown in figure 1, the modeling component includes a block diagram of related chemical reactions. Hucka et al. show that the simulation engine, generates the dynamic behavior of the system using a stochastic computational model (p. 459, sect 5.8-9). Hucka et al. also teaches at page 450, several programs for generating the dynamic behavior, such as Jarnac and Virtual Cell, which reads on the means plus functional language of amended claim 45. Huck et al. further teach at page 459-460 in sections 5.8-5.10 that Jarnac is an ODE-based biochemical network simulator, wherein different mathematical models are implemented for simulating biochemical networks. Applicant defines at paragraph [0095] of the published application that a

composite system has components that fall into the four types of models discussed in previous paragraphs, such as paragraph [0093], wherein the modeling implements difference equations, such as ODEs. Thus, it is being interpreted that a composite graphical model is one which implements difference equations such as ODEs for simulating dynamic behaviors, such as taught by Hucka et al.

Response to Arguments

Applicant's arguments filed 6/8/2009 have been fully considered but they are not persuasive.

Applicant argues that Hucka et al. fails to disclose or suggest executing the composite graphical model to generate as output dynamic behavior of the biological system using a first type of computational model for the first reaction, and a second type of computational model for the second chemical reaction, and the specified constraints, the executing involving the at least two different types of mathematical models.

Applicant's arguments are not found persuasive as Hucka et al. teach at page 452 about SBW using a broker-based architecture, wherein modules are started on demand through user requests or program controls and modules are executables which have their own event loops. In addition, Applicant defines at paragraph [0095] of the published application that a composite system has components that fall into the four types of models discussed in previous paragraphs, such as paragraph [0093], wherein the modeling implements difference equations, such as ODEs. Thus, it is being interpreted that a

composite graphical model is one which implements difference equations such as ODEs for simulating dynamic behaviors, such as taught by Hucka et al.

Applicant further argues that the examiner misconstrues SBW's 'modules."

Applicant's arguments are not found persuasive because it is unclear as to what applicant interprets as SBW's 'modules." SBW interfaces with Jarnac through broker-based messaging to instantiate modules from Jarnac. SBW either through user commands or program controls executes created Jarnac modules, which are comprised of mathematical simulation modules as discussed above. The modules are not part of the internal structures of the SBW software as suggested by applicant. Rather, the modules are formed through the Jarnac application, which are created and destroyed through the SBW interface. The SBW interface enables the instantiation of the Jarnac modules and to run the module simulations created in Jarnac.

Double Patenting-Maintained

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a

nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 and 45-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19, 26 and 64 of copending Application No. 10/783,628. Although the conflicting claims are not identical, they are not patentably distinct from each other.

In the instant case the claims are drawn system computer implemented method and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to display the dynamic behavior. This method with specific steps anticipates the method of the instant claims.

In comparison the claims of copending Application No. 10/783,628 are drawn system computer implemented method and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to display the dynamic

behavior. This method with specific steps anticipates the method of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-22 and 45-48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19, 32, and 38-39 of copending Application No. 10/783,552. Although the conflicting claims are not identical, they are not patentably distinct from each other.

In the instant case the claims are drawn to a system, computer implemented method and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component to generate a model; a simulation engine accepting the model and generating a dynamic behavior for the biologic system; and an analysis environment to display the dynamic behavior. This method with specific steps anticipates the method of the instant claims.

In comparison the claims of copending Application No. 10/783,552, are directed to a system computer implemented method and computer program product for improved modeling of a biological system, a biological system being a plurality of chemical reactions, comprising modeling component with a graphical user interface to generate a model; a simulation engine accepting the model and

generating a dynamic behavior for the biologic system; and an analysis environment to display the dynamic behavior.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments:

Applicant has stated they will submit a terminal disclaimer if the instant claims are deemed allowable.

Conclusion

No claim is allowed.

This is a RCE of applicant's earlier Application No. 10/783,624. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marjorie Moran can be reached via telephone (571)-272-0720.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/ Jason Sims /

/ERIC S. DEJONG/

Primary Examiner, Art Unit 1631